SZABO SCANDIC

Part of Europa Biosite

Produktinformation

- Forschungsprodukte & Biochemikalien
- Zellkultur & Verbrauchsmaterial
- Diagnostik & molekulare Diagnostik
- Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!

Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien

T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

linkedin.com/company/szaboscandic

GloveFAST Cyto Pharma
GloveFAST Cyto Aseptic
Isolators

DASITGROUP

PROTECTION, SAFETY, RELIABILITY
AND MORE.

GloveFAST Cyto Pharma/Aseptic

Faster Isolator for Cytotoxic and Sterility test

THE USER-FRIENDLY PRACTICAL KEYBOARD

ECS® MICROPROCESSOR BASED MONITORING SYSTEM: full status report provided via 2-line digital display by the new generation microprocessors - which automatically control all functions and all safety alarm systems ensuring that performance characteristics are maintained according to safety requirements.

ECS® ECO CONTROLLING SYSTEM

High power lithium battery keeps safety data saved to microprocessor system.

THE USER-FRIENDLY PRACTICAL KEYBOARD and the rear-lit LCD will continuously display all required data keeping the user constantly informed of the cabinet conditions in operation and in particular:

- display of laminar airflow velocity
- display of inside and outside temperature
- display of residual lifetime of H14 HEPA/ULPA filters, UV Lamp (if fitted)
- display of total number of hours of operation
- display of saturation level of H14 HEPA/ULPA filters
- pressure decay-leakage test

AUDIO VISUAL ALARMS PROVIDED FOR

- out of range or incorrect laminar airflow velocity
- saturation of H14 HEPA/ ULPA filters
- end of life-cycle of UV lamp (if fitted)
- blockage in the exhaust duct
- fan-motor malfunction
- power failure
- leakage test

COMPLIANCE

FILTRATION	AIR CLEANLINESS	CONTAINMENT	ELECTRICAL SAFETY
EN 1822 DIN 12980:2005 (for GloveFast Cyto only) IEST-RP-CC00 1.3	ISO 14644-1	ISO 14644-7:2004 “Isolator for Pharmaceutical Application” 2004 “Pharmaceutical Isolators” Pharmaceutical Press 2004	EN 61010-1 EU IEC 61010-1 Worldwide

GloveFAST Cyto Pharma

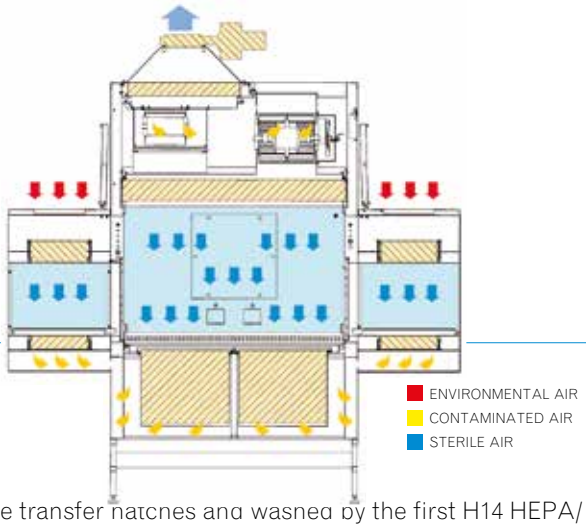
Faster Isolator for cytotoxic applications

SAFETY WITHOUT COMPROMISES

Faster GloveFAST Cyto Pharma cytotoxic isolators are negative pressureglove-box devices which separate a pharmaceutical process or activity both from the operator and the surrounding environment when it comes to reconstitution of lyophilized drugs and toxic materials handling. **Faster GloveFAST Cyto Pharma** units secure from contamination assuring an healthy and safe environment for the operators with a cost-efficient solution. Primarily conceived for safe aseptic handling of hazardous materials such as preparation and handling of **cytotoxic drugs, manipulation of antineoplastic chemo-therapeutics and CMR. Faster GloveFAST Cyto Pharma** is a negative isolator in **Class 3 as per ISO/FDIS 14644-7 with leak tight level measured in 16 Pa/minute** with a real unidirectional airflow in **Class 3 according to ISO 14644-1 or EC GMP Grade A**, isolating the operator and the environment from the process and its constituent parts. **Faster GloveFAST Cyto Pharma** are widely used in hospital pharmacies and oncology clinics for compounding of chemotherapy agents or IV admixtures that can be harmful to pharmacy personnel.

CYTOTOXIC DRUG PREP & FILLING ENHANCED

Daily drug production volumes can be considerably increased by incorporation of a microbiological safety cabinet within the GloveFAST Cyto Pharma Isolators in centralized hospital pharmacy departments.
This increase in output is achieved by allowing the pharmacist to concentrate solely on the reconstitution of the drugs, whilst a second operator will handle batch preparations, cleaning and other ancillary tasks.



WORKING PRINCIPLES

Ambient air is pulled from the inlet positioned on top of the transfer hatches and washed by the first H14 HEPA/ULPA filter bank. Air reaching the hatch volume, is pulled by the negative pressure in the plenum before being filtered in the second bank of H14 HEPA/ULPA filter positioned on the rear hatch panel. Pressurized air pushed into the plenum, is pulled downwards into the working chamber in laminar flow condition by virtue of H14 HEPA/ULPA filter into the working chamber to protect the products handled and avoid cross-contamination. The whole quantity of sterile air is pulled through the perforated work surface into the main H14 HEPA/ULPA filter located below work surface and then re-circulated from the duct channel behind the rear panel. Part of the air is exhausted prior to be filtered by H14 HEPA/ULPA filter, part is pulled again into the working chamber.

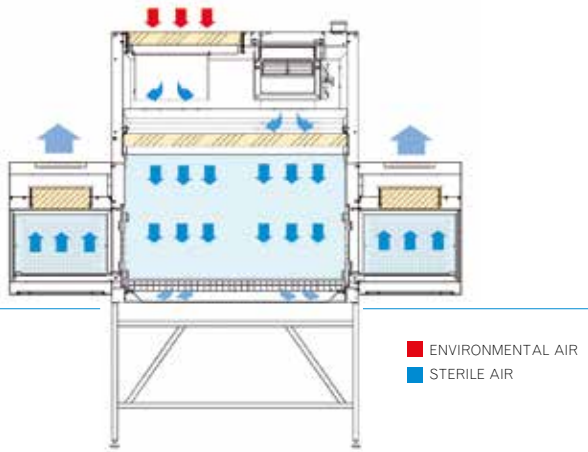
GloveFAST Aseptic

Faster Isolator for Sterility test

STERILITY TESTING

Sterility testing of sterile pharmaceutical products is essential to determine acceptability of a production lot. Required by the Pharmacopoeia as last mandatory control to be performed before release to market distribution, it is an essential element of sterilization validation and it must be performed on sterile drugs and ophthalmic products.

Faster GloveFAST Aseptic is a positive pressure isolator primarily conceived for product protection of non-hazardous drugs providing a positive pressure work. The H14 HEPA/ULPA filtered unidirectional airflow of better than Class ISO 3 air cleanliness conditions, prevents from contaminants from the outside entering the main and transfer chambers. Being a completely closed system, **Faster GloveFAST Aseptic** isolator allows operators to perform sterility testing in an aseptic environment providing assurance of material integrity.
Faster GloveFAST Aseptic is the solution for laboratory sterility testing.



WORKING PRINCIPLES

Ambient air is pulled from the H14 HEPA/ULPA filter inlet positioned on top of the isolator and then pressurized downwards towards the work surface prior to be H14 HEPA/ULPA filtered by the main filter. The air is partially re-circulated and partially exhausted via side transfer hatches before being washed again by virtue of a double set of H14 HEPA/ULPA filters fitted inside the hatches.

GloveFAST Cyto Pharma/Aseptic

Faster Isolator for Cytotoxic and Sterility test

COMMON FEATURES

CONSTRUCTION

Full body of the unit and transfer hatches made in epoxy painted steel coated with Alesta® Dupont anti-microbial painting. Full AISI 304L stainless steel body carcass and hatches available as option.

WORKING SURFACES

Fully made in AISI 316L stainless steel with scotch brite finishing.
Back walls in AISI 304L stainless steel.

FILTRATION

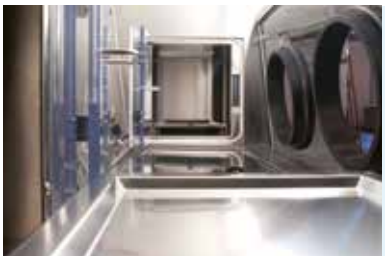
Filtration is provided by seven absolute filters H14 HEPA/ULPA with typical efficiency of 99.995% MPPS according to CEN EN 1822 and 99.999% conforming to IEST-RP CC00 1.3 USA. All the filters are low pressure drop certified H14 HEPA/ULPA filters. Transfer hatches are equipped with a set of inlet and re-circulating filters whilst the body of the isolator is equipped with a full set of main, exhaust and special bag filters for cytotoxic containment.

GLASSES

Frontal window made in 12mm safety glass. Internal and external transfer hatch doors are made in transparent high resistance P.E.T.G. polyester resin. The frontal view-screen is slanted with top hinges that allow full opening for loading and unloading of pharmacy instrumentations.

OUTLETS

Two electrical outlets supplied as standard in 4ft model and four in 5ft/6ft model. Various data sockets available upon request as option.



WORKING SURFACES

Working surfaces made in AISI 316L stainless steel scotch brite finishing. Back wall made in AISI 304L. All internal working chamber surfaces are cleanable directly from the inside with no need to open the frontal window.

GLOVES

The glove set features 300mm poly-propylene O-Ring flanges connected to coated PVC textile sleeves.
Gloves are made in neoprene.

TRANSFER HATCHES

GloveFAST Cyto Pharma/Aseptic transfer hatches are C2 type according to ISO-FDIS 14644-7.
The internal surfaces are made in AISI 304/316L stainless steel whilst external body carcass is made in epoxy painted steel. The hatches are fitted with one piece P.E.T.G. polyester resin doors with electro-magnetic interlock system.
Construction fully made in stainless steel is available upon request.

VALVE

Pneumatic or electric valve to perform decontamination processes and leakage test, available as option.

TRANSFER HATCHES SLIDING WORK SURFACE

Transfer hatches sliding trays made in AISI 316L stainless steel ease the transfer of materials inside out the working volume.
The trays are removable for sterilization processes in autoclave.

BACK SIDE WALL

Back side wall custom fitting for LCD 15" screen installation available as option.

DEHS RAPID TEST PORTS

Rapid DEHS test ports to perform integrity filter test of each H14 HEPA/ULPA filter installed inside the isolator.

TECHNICAL SPECIFICATIONS

Description		GloveFAST Cyto Pharma/Aseptic		
		GF 2-4-2 2 hatches/4 ft/2 gloves	GF 2-5-3 2 hatches/5 ft/3 gloves	GF 2-6-4 2 hatches/6 ft/4 gloves
Dimensions	*Unit*			
Overall (WxHxD)	mm	2670x1950x880	2975x1950x880	3280x1950x880
Useful (WxHxD)	mm	1192x740x580	1497x740x580	1802x740x580
Transfer hatch overall WxHxD	mm	660x730x658	660x730x658	660x730x658
Transfer hatch useful WxHxD	mm	615x335x455	615x335x455	615x335x455

Construction	
Body	Epoxy powder painted steel coated with Alesta® Dupont antimicrobial painting
Transfer hatch	Epoxy powder painted steel coated with Alesta® Dupont antimicrobial painting
Work surface	AISI 316L stainless steel, 4B finishing with thickness of 1.2 mm and 1.5 mm

Filtration	
Transfer hatch	Inlet low pressure drop certified H14 HEPA filters with typical efficiency of 99,995% MPPS CEN EN 1822-ULPA filter with typical efficiency of 99,999% at 0.1 to 0.3 µm as per IEST-RP-CC00 1.3 USA
	Recirculating low pressure drop certified H14 HEPA filters with typical efficiency of 99,995% MPPS CEN EN 1822-ULPA filter with typical efficiency of 99,999% at 0.1 to 0.3 µm as per IEST-RP-CC00 1.3 USA
Working volume	Main low pressure drop certified H14 HEPA filters with typical efficiency of 99,995% MPPS CEN EN 1822-ULPA filter with typical efficiency of 99,999% at 0.1 to 0.3 µm as per IEST-RP-CC00 1.3 USA
	Cytotoxic low pressure drop certified H14 HEPA filters with typical efficiency of 99,995% MPPS CEN EN 1822-ULPA filter with typical efficiency of 99,999% at 0.1 to 0.3 µm as per IEST-RP-CC00 1.3 USA
	Exhaust low pressure drop certified H14 HEPA filters with typical efficiency of 99,995% MPPS CEN EN 1822-ULPA filter with typical efficiency of 99,999% at 0.1 to 0.3 µm as per IEST-RP-CC00 1.3 USA
Glasses	Frontal and side stratified safety glasses
Gloves and sleeves	Polypropilene 300 mm supporting ring for the sleeves with O-Ring system for gloves and textile sleeves replacement. Neoprene gloves and sleeves

AVAILABLE OPTIONS FOR GLOVEFAST CYTO PHARMA AND ASEPTIC

• Construction fully made in AISI 304L stainless steel • ATV DN150 electric or pneumatic gauge for automatic pressure decay test • Hanging rails for bags • Back side wall LCD screen window (screen not included) • Anti blowback valve • Automatic adjustable height supporting stand (work surface height from 770 mm to 1070 mm) • In&Out plug doors and internal circuit for hydrogen peroxide generators connection.

DASITGROUP

FASTER FOR A GREEN FUTURE

Striving everyday to improve our environmental performance, Faster developed environmental procedures are founded on three guiding principles:

Protect the Environment for present and future generations manufacturing low energy consumption equipments

Reduce risks and improve efficiencies

Introduce improved technology and processes

Faster S.r.l.
Via R. Merendi, 22 20010 Cornaredo (MI) Italy
Tel +39 02 93 991 92 Fax +39 02 93 991 608
www.faster-air.com info@faster.dgroup.it